

REMARKS

Claims 1, 2, 4, 5, 7, 8, 10, 12, 13, 15-19 and 21-22 are currently pending in the present application. The Office Action is non-final. Claims 2, 4, 5, 7, 8, 10, 12, 13, 15-19, 21 and 22 are withdrawn from further consideration as being directed to a non-elected invention. Claims 1-5, 7, 12, 13 and 15 have been amended to more accurately reflect the claimed invention. Support for the amendment to claims 1-5, 7, 12, 13 and 15 can be found in the original claims and pages 20-21 of the specification. No new matter has been added by way of this amendment. Claims 1, 3 and 20 stand rejected.

Examined claims 1, 3 and 20 considered together with the following remarks are believed sufficient to place the application into condition for allowance. Accordingly, an early and favorable action on the merits is earnestly solicited at present.

Restriction Requirement made FINAL

With regards to the Restriction Requirement made FINAL, Applicants preserve the right of petition from this Requirement for Restriction under 37 C.F.R. § 1.144 and Applicants reserve the right to file one or more continuing applications on the withdrawn claims. However, since claim 1 in the corresponding European patent application is restricted to a composition comprising antigens of the U.S. claims 1, 3 and 20, i.e. the antigens of the claims under consideration, Applicants have amended claim 1 to correspond to the EP claim 1. This claim has recently been allowed in the corresponding European application. In the event of rejoinder, the restriction requirement between the antigenic composition claims and the rejoined claim methods will be withdrawn, wherein the rejoined method claims will be fully examined for patentability in accordance with 37 CFR 1.104.

Applicants have elected the antigen combination (2) EAG, SEC and Sc1C. Once the elected species is found to be allowable, the Examiner is requested to expand the examination of the claims to the non-elected species.

Information Disclosure Statement

The Examiner is respectfully requested to acknowledge the Information Disclosure statement which was filed on November 28, 2005. A copy of the IDS (*PTO-1449, with USPTO date stamp*) has been attached for the Examiner's Convenience.

Issue Under 35 U.S.C. § 101 Non-statutory Subject Matter

The Examiner has rejected claims 1, 3 and 20 under 35 C.F.R. § 101 because the claimed invention is directed to non-statutory subject matter. The claimed invention is drawn to a protein product of nature.

Reconsideration and withdrawal of the above rejection is respectfully requested based on this amendment.

In response to this rejection, Applicants have amended claim 1 to recite:

An isolated antigenic composition...

Applicants argue that the term "isolated", reflect the "hand of man" in the production of the product, and not a protein product of nature.

Issues Under 35 U.S.C. § 112, Second Paragraph, Indefiniteness

The Examiner has rejected claim 20 under 35 C.F.R. § 112, second paragraph as being indefinite for the recitation of " ... comprises at least part of a protein designated Scl and comprising an amino acid sequence according to SEQ ID NO:23 or a fragment thereof, suitably a fragment designated SCL C1 and comprising an amino acid sequence according to SEQ ID NO:27 or an analog thereof." The use of the term "suitably" makes it unclear whether the limitation following the phrase (i.e. a fragment designated SCL C1 and comprising an amino acid sequence according to SEQ ID NO:27) is part of the claimed invention. Further, from the claim language, it appears the SCL C1 (SEQ ID NO:27) is a fragment of Scl (SEQ ID NO:23). However, an examination of these sequences reveals that SEQ ID NO:27 is not a fragment of SEQ ID NO:23. Finally, it is not clear whether the phrase "or an analog thereof" is meant to apply to SEQ ID NO:23, a fragment of SEQ ID NO:23, or SEQ ID NO:27.

Reconsideration and withdrawal of the above rejection is respectfully requested based on this amendment.

In response to this rejection, Applicants have amended claim 1 and cancelled claim 20.

Amended claim 1 recites that the third antigen is comprised of amino acid sequence of SEQ ID NO:23 and the immunogenic fragment of Sc1C, which fragment comprises the amino acid sequence of SEQ ID NO:27. In amended claim 1, the subject matter of original claim 20 has been inserted into claim 1 in the section (iii) wherein the third antigen of the present antigenic composition is defined. Since it does not contain the terms "suitably" and "analog" which terms the Examiner has rejected, the definition of the third antigen in the section (iii) is not vague and indefinite.

Furthermore, regarding the relationship between the protein of SEQ ID NO:23 and the protein of SEQ ID NO:27, these sequences are referred to the specification at pages 20-21 from which it is evident that a protein designated Sc1C comprises an amino acid sequence shown as SEQ ID NO:23. In comparison to this amino acid sequence which is shown as SEQ ID NO:23, the amino acid sequence shown as SEQ ID NO:27 is shorter and lacks not only the amino acid residue numbers 2-37, but also the terminal amino acid residue numbers 270-302 of the sequence shown as SEQ ID NO:23. Therefore, the protein of SEQ ID NO:27 is a fragment of the protein of SEQ ID NO:23. In amended claim 1, it is in connection with the third antigen referred to as "Sc1C" (supported in the specification on page 20). Reference to "Sc1" in the original claim 20 was in error.

Issues Under 35 U.S.C. § 102(b), Anticipation

The Examiner has rejected claims 1, 3 and 20 under 35 C.F.R. § 102(b) as being anticipated by **Lindmark et al. (Res. Vet. Sci., 66:93-99, 1999, IDS filed 6/22/2005)**.

Reconsideration and withdrawal of the above rejection is respectfully requested based on this amendment.

Amended claim 1 is drawn to a purified (**3-sectioned domain**) antigenic composition comprised of:

- (i) a first antigen, which first antigen comprises at least part of an isolated protein of *Streptococcus equi* subsp *equi*, which protein is designated EAG and which at least part of

said protein comprises at least one antigenic epitope or antigenic determinant of *Streptococcus equi*, and

which first antigen comprises at least the N-terminal amino acid sequence of EAG, which comprises the amino acid sequence of SEQ ID NO:1,

(ii) a second antigen, which second antigen comprises at least part of an isolated protein of *Streptococcus equi*, which protein is designated SEC and comprises the amino acid sequence of SEQ ID NO:4, and which at least part of said protein comprises at least one antigenic epitope or antigenic determinant of *Streptococcus equi*, and

which second antigen comprises at least the N-terminal collagen-binding part of SEC which comprises the amino acid sequence of SEQ ID NO:22, and

(iii) a third antigen, which third antigen comprises at least part of an isolated protein of *Streptococcus equi*, which protein is designated Sc1C and comprises the amino acid sequence of SEQ ID NO:23 and which at least part of said protein comprises at least one antigenic epitope or antigenic determinant of *Streptococcus equi*, and

which third antigen comprises at least the immunogenic fragment of Sc1C, which fragment comprises the amino acid sequence of SEQ ID NO:27.

In responding to this rejection, it appears that Lindmark *et al.* is relevant in teaching a method for distinguishing between different isolates of *Streptococcus equi*. Although it refers to earlier studies wherein two cell surface proteins, which are termed ZAG and FNZ and are contained in the *Streptococcus equi* subspecies *zooepidemicus* strain ZV, this ZAG protein from subspecies *zooepidemicus* is not the same or identical to the claimed EAG protein from subspecies *equi* which is used in the antigenic composition of the present invention.

Moreover, the Lindmark *et al.* reference does not disclose expression of the *eag* gene, carried by subspecies *equi*, required to produce the EAG protein of the present invention and contains no disclosure of the protein EAG comprising the amino acid sequence identified as SEQ ID NO:1.

Since the Lindmark *et al.* reference does not disclose expression of the gene, which according to the present invention termed *eag* and is carried by subspecies *equi*, the subject matter as claimed is novel over Lindmark *et al.* Applicants argue that the *eag* gene is similar but not identical to the *zag* gene, thus the claimed isolated antigenic composition comprising the

EAG protein is novel. Additionally the combination of proteins domains (ii) and (iii) must also be novel.

The Lindmark *et al.* reference does not teach the limitation of the claimed SEQ ID NO:s.

Legal Standard For Anticipation

The standard for a rejection under 35 U.S.C. § 102(b) is established in MPEP §2131. A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. If an independent claim is allowable under 35 U.S.C. § 102, then any claim depending therefrom is also allowable.

Therefore, it is submitted that Lindmark *et al.* does not teach each and every limitation of the present claimed invention.

Accordingly, the present invention is not anticipated by the **Lindmark *et al.*** reference of record. Any contention of the USPTO to the contrary must be reconsidered at present. Reconsideration and withdrawal of the above rejections are respectfully requested based on the above-considerations.

CONCLUSION

In view of the above amendment, applicant believes the pending application is in condition for allowance.

Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact Eggerton A. Campbell Reg. No. 51,307 at the telephone number of the undersigned below, to conduct an interview in an effort to expedite prosecution in connection with the present application.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37.C.F.R. §§1.16 or 1.17; particularly, extension of time fees.

Dated: November 25, 2008

Respectfully submitted,

for By *L. L. T. Parker, Reg. No. 46046*
Gerald M. Murphy, Jr.
Registration No.: 28,977
BIRCH, STEWART, KOLASCH & BIRCH, LLP
8110 Gatehouse Road
Suite 100 East
P.O. Box 747
Falls Church, Virginia 22040-0747
(703) 205-8000
Attorney for Applicant